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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,322	02/25/2004	Daniel M. LaFontaine	10527-437002	2641
26191 7590 12/30/2009 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER GIBSON, ROY DEAN				
ART UNIT		PAPER NUMBER		
3739				
NOTIFICATION DATE		DELIVERY MODE		
12/30/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

### Office Action Summary

**Application No.**

10/786,322

**Applicant(s)**

LAFONTAINE, DANIEL M.

**Examiner**

Roy D. Gibson

**Art Unit**

3739

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 43, 44, 46, 49 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43, 44, 46, 49 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 8/13/2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include reference sign(s) for the first and second balloon nor are there reference signs or numbers for these elements in the Specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

In addition, the reference numbers should be added to the Specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43, 44, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittenberger et al. (6,575,933) in view of Hammack et al.

(6,679,906). Wittenberger et al. disclose a device for minimally invasive medical treatment in a body of a patient, comprising:

a tubular member (600) having a proximal end and a distal end;

a cryo therapy apparatus (Figure 13) connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon (610) and a second balloon (630), the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails;

wherein the cryo therapy apparatus is sized and arranged for vascular introduction (col. 5, lines 35-67 and col. 8, lines 17-38). However, Wittenberger et al. fail to specifically disclose an optical sensor to monitor temperatures created by use of the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus. But, Hammack et al. disclose a catheter with an on-board optical temperature sensor which meets all of the limitations not disclosed by Wittenberger et al. (Figures 1-5 and col. 10, lines 34-51). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Wittenberger et al., as taught by Hammack et al., to provide an optical sensor, quantification device and separate lumen as required for monitoring an ice ball formation and temperature.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wittenberger et al . in view of LePivert (6,551,309). Wittenberger et al . disclose a device for minimally invasive medical treatment in a body of a patient, comprising:

a tubular member having a proximal end and a distal end; a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the crvo therapy apparatus if the first balloon fails and body of the patient;

wherein the cryo therapy apparatus is sized and arranged for vascular introduction (col. 5, lines 35-67 and col. 8, lines 17-38).

But, Wittenberger et al fails to specifically disclose an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus. However, LePivert discloses an optical imaging apparatus (CIS 17) near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus (col. 10, lines 34-51). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Wittenberger et al , as taught by LePert, to provides such an optical imaging device to monitor temperatures resulting from use of the cryo therapy device.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/  
Primary Examiner  
Art Unit 3739

December 22, 2009